

Exhibit 3

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

- - -

4 IN RE: VALSARTAN, : MDL NO. 2875
5 LOSARTAN, AND :
6 IRBESARTAN PRODUCTS : CIVIL NO.
7 LIABILITY LITIGATION : 19-2875
8 : (RBK/JS)

9 :
10 THIS DOCUMENT APPLIES : HON. ROBERT
11 TO ALL CASES : B. KUGLER
12 - CONFIDENTIAL INFORMATION -
13 SUBJECT TO PROTECTIVE ORDER

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 I N D E X
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Testimony of:
 By Mr. Slater JUN DU 226

- - -
 E X H I B I T S
 - - -

NO.	DESCRIPTION	PAGE
ZHP-433	Isolation and Identification Of Process Impurities (Jing Nie)	244
ZHP-434	E-mail Thread 11/2/18 Subject, Happy Chinese New Year!	275
	ZHP 00675949-56	

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- - -
 P R E V I O U S L Y M A R K E D
 E X H I B I T S
 - - -

NO.	DESCRIPTION	PAGE
ZHP-204	Deviation Report ZHP 00004352-71	287
ZHP-212	Investigation Report 6/6/18 ZHP 00662283-09	251
ZHP-213	Warning Letter 11/29/18 ZHP 01344159-64	234
ZHP-312	Establishment Inspection Report 7/23/18 PRINSTON 00162349-06	230
ZHP-319	E-mail Thread 7/17/18 Subject, Hello and Help CHARLESWANG 000447-49	280
ZHP-321	Concise International Chemical Assessment Document 38 NDMA WHO 2002	288

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 D E P O S I T I O N S U P P O R T I N D E X
 - - -

Direction to Witness Not to Answer
 PAGE LINE
 None.

Request for Production of Documents
 PAGE LINE
 None.

Stipulations
 PAGE LINE
 None.

Questions Marked
 PAGE LINE
 None.

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- - -

THE VIDEOGRAPHER: We are now on the record.

My name is Judy Diaz, I'm a legal videographer for Golkow Litigation Services.

Today's date is May 28, 2021, and the time is 9:12 a.m.

This remote video deposition is being held in the matter of valsartan, losartan, and irbesartan products liability litigation MDL.

This is the continuation of the deponent Jun Du.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All counsel will be noted on the stenographic record.

The court reporter is Michelle Gray.

The witness and interpreter

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1 are already under oath.
 2 - - -
 3 ... YANG SHAO and EVELYN
 4 YANG GARLAND, having been
 5 previously duly sworn, translated
 6 Chinese to English, as follows:
 7 - - -
 8 ... JUN DU, having been
 9 previously sworn, was examined and
 10 testified as follows:
 11 - - -
 12 CONTINUED EXAMINATION
 13 - - -
 14 BY MR. SLATER:
 15 Q. On the screen we have
 16 Exhibit 430.
 17 Let's look at the bottom
 18 paragraph on the first page please.
 19 This is your letter to the
 20 FDA August 26, 2018.
 21 The bottom paragraph says --
 22 MR. SLATER: I'm sorry.
 23 I'll start over.
 24 THE WITNESS: Can you give

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1 me a few seconds to take a look at
 2 this document?
 3 BY MR. SLATER:
 4 Q. Yeah, all right. I didn't
 5 even -- I was halfway through my question
 6 so I'll start over. But you can go ahead
 7 and look first.
 8 MR. SLATER: Keep track of
 9 the time, please.
 10 THE WITNESS: I'm ready.
 11 BY MR. SLATER:
 12 Q. Looking now at Exhibit 430,
 13 which is your August 26, 2018 letter to
 14 the FDA. I want to look at the bottom
 15 paragraph on Page 1.
 16 You wrote in this letter,
 17 "One of the key questions about this
 18 inspection as well as about our own
 19 investigation is," quote -- and quoting
 20 what the FDA asked -- "why NDMA was not
 21 detected or considered during the process
 22 change from the triethylamine process to
 23 zinc chloride process."
 24 Do you see where that's

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1 stated at the bottom of the letter?
 2 A. Yes.
 3 Q. One thing I just want to
 4 clarify is, in retrospect you also found
 5 out that there was NDMA and NDEA from the
 6 TEA process, the triethylamine process
 7 with sodium nitrite quenching. It turned
 8 out that also had the nitrosamine
 9 contamination, correct?
 10 A. One, that question was
 11 responded at that time. The issue of TEA
 12 or NDEA was not discovered yet. Besides
 13 NDEA is not a contaminant, it is an
 14 impurity rather.
 15 Q. Your response states, "As
 16 revealed by our investigation, the
 17 ultimate reason for the presence of NDMA
 18 in valsartan API is due to this process
 19 change in which the solvent
 20 dimethylformamide (DMF) was introduced
 21 and its impurity/degradant,
 22 dimethylamine, unexpectedly reacts with
 23 nitrous acid (generated in situ between
 24 sodium nitrite and hydrochloric acid)

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1 during the subsequent quenching step in
 2 the presence of the product of that
 3 step."
 4 That is what you told the
 5 FDA in terms of why the NDMA formed with
 6 the zinc chloride process, correct?
 7 A. That is correct. That's
 8 what this letter says.
 9 Q. And that change to the zinc
 10 chloride process which led to this
 11 process impurity of NDMA allowed you, and
 12 allowed ZHP, to reduce costs and increase
 13 yield for the valsartan API, correct?
 14 A. I believe it should be put
 15 in this way. Why we changed the process
 16 was to improve the yield and reduce the
 17 waste. This would be a process that any
 18 API manufacturer would pursue and with
 19 the term "fast, effective." This is
 20 rather a normal activity or practice.
 21 MR. SLATER: Cheryll, let's
 22 digress for a moment and go to
 23 Exhibit 312, please, and then
 24 we'll come back to this document.

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1 Let's go if we could, to the
 2 cover first.
 3 (Previously marked Exhibit
 4 ZHP-312.)
 5 BY MR. SLATER:
 6 Q. Looking at Exhibit 312, this
 7 is the FDA establishment inspection
 8 report for the inspection from July 23,
 9 2018 to August 3, 2018. Do you see that
 10 on the screen?
 11 A. Hold on, let me take a look.
 12 Excuse me, what exhibit
 13 number is this?
 14 Q. 312.
 15 A. Thank you. I see it.
 16 Q. Let's go, if we could, to
 17 Page 25 of 58; the Bates number at the
 18 bottom is Princeton00162373 for that page.
 19 Perfect.
 20 A. Please allow me a few
 21 seconds to review this EI report.
 22 MR. SLATER: Keep track of
 23 the time, please.
 24 THE WITNESS: I'm ready. I

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1 just finished reviewing.
 2 BY MR. SLATER:
 3 Q. Looking now at the
 4 paragraph, the short paragraph --
 5 rephrase.
 6 Looking at the paragraph in
 7 the middle of the page which is reciting
 8 the discussions with the FDA
 9 investigators, it states in part,
 10 "Mr. Jun Du, executive vice president,
 11 apologized and stated the change control
 12 should have stated the purpose of the
 13 change was to save money. Mr. Du further
 14 stated the cost reduction was so
 15 significant it is what made it possible
 16 for the firm to dominant the world market
 17 share."
 18 The process change that's
 19 being discussed there is the change to
 20 the zinc chloride process, correct?
 21 A. Hold on. I'm scrolling to
 22 this page.
 23 Yes, I see it. That's what
 24 the EI report says.

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1 Q. Let's go back now to --
 2 A. However, I do not agree with
 3 the statement here. I did not make such
 4 an apology, and I do not understand why
 5 it was written here. I did not state
 6 that the cost reduction would cause
 7 dominant world market share.
 8 Q. Let's go back to Exhibit 430
 9 please. Let's look now at Page 2 of the
 10 letter.
 11 Let's look now at the third
 12 paragraph on the page, please. Can
 13 you -- rephrase.
 14 Your letter to the FDA
 15 states in the third paragraph on Page 2,
 16 in the current -- excuse me, I've got to
 17 start over.
 18 Looking at Paragraph 3 on
 19 Page 2 now, your letter states, "In the
 20 current NDMA event, it is not the
 21 residual DMF that reacts with nitrous
 22 acid of the next step, but rather it is
 23 the trace amount of dimethylamine, an
 24 impurity/degradant of DMF that reacts

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1 with nitrous acid to form NDMA, which
 2 adds a further dimension over the current
 3 thinking, logic and strategy for the
 4 evaluation of potential genotoxic
 5 impurities. It is this extra dimension
 6 over the current industry practice that
 7 obscured us from foreseeing this impurity
 8 during the process change from
 9 triethylamine process to zinc chloride
 10 process."
 11 That's what you told the FDA
 12 in this letter to try to explain why your
 13 company didn't realize when they
 14 instituted the zinc chloride process that
 15 it would be bringing in a risk of
 16 creating NDMA, right?
 17 A. What are you referring to by
 18 "the company"?
 19 Q. ZHP, who you were -- who you
 20 were writing on behalf of -- rephrase.
 21 ZHP, on whose behalf you
 22 were writing this letter as executive
 23 vice president.
 24 A. That is correct. That's

<p style="text-align: right;">Page 234</p> <p>1 what ZHP wrote.</p> <p>2 Q. You signed the letter as</p> <p>3 executive vice president of the company,</p> <p>4 right?</p> <p>5 A. That is correct. I signed</p> <p>6 this letter on behalf of ZHP.</p> <p>7 MR. SLATER: Let's go now,</p> <p>8 Cheryl if we could to</p> <p>9 Exhibit 213, the FDA's response.</p> <p>10 (Previously marked Exhibit</p> <p>11 ZHP-213.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. On the screen we have</p> <p>14 Exhibit 213, which is the FDA's</p> <p>15 November 29, 2018 letter written in</p> <p>16 response to your August 26, 2018 letter</p> <p>17 that we were just discussing.</p> <p>18 A. Could you give me a few</p> <p>19 seconds to review this document. I am</p> <p>20 ready.</p> <p>21 Q. First of all, in the middle</p> <p>22 of the first page the fourth paragraph</p> <p>23 down states, "We reviewed your August 26,</p> <p>24 2018 response in detail and acknowledge</p>	<p style="text-align: right;">Page 236</p> <p>1 If you try to find out what they</p> <p>2 specifically referred to, you have to</p> <p>3 resort to the text below.</p> <p>4 MR. GOLDBERG: Just note my</p> <p>5 objection to the last question as</p> <p>6 calling for a legal conclusion.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Going up one more paragraph,</p> <p>9 there's a single sentence paragraph that</p> <p>10 says, "This warning letter summarizes</p> <p>11 significant deviations from current good</p> <p>12 manufacturing practice (cGMP) for active</p> <p>13 pharmaceutical ingredients (API)."</p> <p>14 And what I'd like to now do</p> <p>15 is go through one of the specifics. If</p> <p>16 we can turn now to Page 4 of the letter,</p> <p>17 which the Bates stamp is ZHP01344162 for</p> <p>18 that page so we can look at one of the</p> <p>19 specific examples.</p> <p>20 And number -- rephrase.</p> <p>21 Number 2, "Failure to</p> <p>22 evaluate the potential effect that</p> <p>23 changes in the manufacturing process may</p> <p>24 have on the quality of your API."</p>
<p style="text-align: right;">Page 235</p> <p>1 receipt of your subsequent</p> <p>2 correspondence."</p> <p>3 The August 26th letter is</p> <p>4 the letter we were just discussing prior</p> <p>5 to this document, correct?</p> <p>6 A. That is correct.</p> <p>7 Q. Just above the sentence that</p> <p>8 I just read, the FDA informed you, on</p> <p>9 November 29, 2018, "Because your methods,</p> <p>10 facilities, or controls for</p> <p>11 manufacturing, processing, packing, or</p> <p>12 holding do not conform to cGMP, your API</p> <p>13 are adulterated within the meaning of</p> <p>14 Section 501(a)(2)(B) of the Federal Food,</p> <p>15 Drug, and Cosmetic Act, 21 U.S.C.</p> <p>16 351(a)(2)(B)."</p> <p>17 Do you know what adulterated</p> <p>18 means?</p> <p>19 A. I do.</p> <p>20 Q. What does adulterated mean?</p> <p>21 A. What they meant was that it</p> <p>22 was involved in a fraud or fake</p> <p>23 substance. However, this is their</p> <p>24 uniform statement in the warning letter.</p>	<p style="text-align: right;">Page 237</p> <p>1 Again, the change they're</p> <p>2 talking about here is the change to the</p> <p>3 zinc chloride process, right?</p> <p>4 A. What they discussed here was</p> <p>5 the zinc chloride process change for</p> <p>6 valsartan.</p> <p>7 Q. The FDA specifically states,</p> <p>8 "In November 2011 you approved a</p> <p>9 valsartan API process change (PCRC -</p> <p>10 110125) that included the use of the</p> <p>11 solvent DMF."</p> <p>12 That is what occurred as</p> <p>13 part of the zinc chloride process change,</p> <p>14 correct?</p> <p>15 A. That is correct. It was</p> <p>16 also approved by the FDA.</p> <p>17 Q. Your -- rephrase.</p> <p>18 The FDA continues, "Your</p> <p>19 intention was to improve the</p> <p>20 manufacturing process, increase product</p> <p>21 yield, and lower production costs.</p> <p>22 However, you failed to adequately assess</p> <p>23 the potential formation of mutagenic</p> <p>24 impurities when you implemented the new</p>

<p style="text-align: right;">Page 238</p> <p>1 process. Specifically, you did not 2 consider the potential for mutagenic or 3 other toxic impurities to form from DMF 4 degradants, including the primary DMF 5 degradant, dimethylamine. According to 6 your ongoing investigation, dimethylamine 7 is required for the probable human 8 carcinogen NDMA to form during the 9 valsartan API manufacturing process. 10 NDMA was identified in valsartan API 11 manufactured at your facility." 12 And I want to stop there and 13 just confirm, when they talk about NDMA 14 was identified, they are talking about 15 NDMA in the valsartan API that was 16 manufactured with the zinc chloride 17 process, correct? 18 A. The -- that is correct. The 19 FDA opined here that, retrospectively 20 speaking, after the discovery of the 21 formation of NDMA, the decomposition or 22 degradation of DMF was not considered in 23 the process change. However, when FDA 24 approved this process change, they did</p>	<p style="text-align: right;">Page 240</p> <p>1 it, and used it to manufacture the API 2 and finished dose that ZHP sold, correct? 3 A. What you just read was 4 indeed the content of this warning letter 5 from the FDA. 6 Could you please repeat your 7 question? 8 Q. When the FDA refers to your 9 manufacturing processes, that is correct, 10 ZHP developed the zinc chloride 11 manufacturing process, ZHP implemented 12 it, and the API manufactured with that 13 process was sold by ZHP, correct? 14 A. The process change referred 15 to here was the zinc chloride process 16 change, which was also approved by the 17 FDA and used by ZHP in their 18 manufacturing. Princeton as the ANDA 19 holder also used the API approved by the 20 FDA. Our company also sold this product 21 in the U.S. market. 22 In addition, with regard to 23 the questions raised in this warning 24 letter from the FDA, ZHP provided their</p>
<p style="text-align: right;">Page 239</p> <p>1 not consider the degradation of DMF 2 either. Therefore, FDA considered this 3 impurity as an unexpected impurity. 4 Q. The next paragraph of the 5 letter states -- rephrase. 6 The next paragraph of the 7 letter from the FDA says, "You also 8 failed to evaluate the need for 9 additional analytical methods to ensure 10 that unanticipated impurities were 11 appropriately detected and controlled in 12 your valsartan API before you approved 13 the process change. You are responsible 14 for developing and using suitable methods 15 to detect impurities when developing, and 16 making changes to your manufacturing 17 processes. If new or higher levels of 18 impurities are detected, you should fully 19 evaluate the impurities and take action 20 to ensure the drug is safe for patients." 21 And when the FDA pointed out 22 that this was ZHP's manufacturing 23 process, that was correct, ZHP developed 24 the zinc chloride process, implemented</p>	<p style="text-align: right;">Page 241</p> <p>1 own responses to each and every question 2 in this warning letter, including their 3 explanations or clarifications, their own 4 opinions, as well as related improvement 5 actions such as CAPA actions. 6 If you want to find out the 7 opinion of ZHP, please review the 8 response to this warning letter. 9 To the best of my personal 10 understanding, FDA accepted our response. 11 Q. When you refer -- rephrase. 12 When the FDA refers to your 13 manufacturing processes here, the one 14 that they are specifically talking about 15 is the zinc chloride manufacturing 16 process for valsartan, correct? 17 A. The manufacturing process 18 referred to in the document we are 19 looking at right now is indeed the zinc 20 chloride process change, judging from the 21 process change number. 22 Q. The last sentence of this 23 paragraph that states, "If new or higher 24 levels of impurities are detected, you</p>

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1 should fully evaluate the impurities and
 2 take action to ensure the drug is safe
 3 for patients."
 4 You agree that ensuring the
 5 drug is safe for patients needs to be the
 6 most important thing that ZHP should have
 7 done, correct?
 8 A. In response to your
 9 question, the statement you just quoted
 10 was regarding to -- our response to their
 11 483 letter. The FDA's opinion was that
 12 our original response was not sufficient.
 13 We should continue to evaluate and take
 14 corrective actions to ensure the safety
 15 of the drugs. That is my personal
 16 opinion.
 17 Once again, with regard to
 18 all the questions raised in this letter,
 19 ZHP had already provided an official or
 20 formal response.
 21 Q. The last sentence of this
 22 paragraph states, "If new or higher
 23 levels of impurities are detected, you
 24 should fully evaluate the impurities and

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1 take action to ensure the drug is safe
 2 for patients."
 3 I want to focus on the last
 4 part, "ensuring the drug is safe for
 5 patients."
 6 Do you agree that is the
 7 most important rule that you need to
 8 follow, and that ZHP needed to follow, in
 9 manufacturing drugs for sale to patients?
 10 MR. GOLDBERG: Objection to
 11 form. Misstates testimony.
 12 THE WITNESS: To any drug
 13 manufacturer, ensuring the
 14 product -- let me put it this way.
 15 Let me start all over again.
 16 To any drug manufacturer
 17 utilizing their utmost knowledge
 18 and effort to ensure the safety to
 19 the patient for any of their
 20 product is correct.
 21 This statement is correct.
 22 MR. SLATER: Cheryll, I want
 23 to go to another document. Don't
 24 lose this. We'll come right back

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1 to it.
 2 I want to go to an article
 3 titled Isolation and
 4 Identification of Process
 5 Impurities in Crude Valsartan.
 6 There we go.
 7 Just for the record what
 8 exhibit number is this?
 9 MS. CALDERON: 433.
 10 (Document marked for
 11 identification as Exhibit
 12 ZHP-433.)
 13 BY MR. SLATER:
 14 Q. 433. Thank you.
 15 Looking now at Exhibit 433,
 16 this is an article that was published in
 17 the Journal of Liquid Chromatography &
 18 Related Technologies in 2006.
 19 And if we could, let's go to
 20 the second page so we can see who the
 21 authors are.
 22 Do you see there's three
 23 authors, and the third one is Danhua Wang
 24 from ZHP?

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1 A. I see it.
 2 Q. So this is an article
 3 published in 2006 in a medical journal
 4 and one of the authors was a ZHP
 5 employee. You see that, correct?
 6 A. I see it. However, could
 7 you please give me a few seconds to
 8 review this document, because I've never
 9 seen this document before, nor do I have
 10 the relevant technical knowledge.
 11 MR. SLATER: Let's keep time
 12 on this.
 13 THE WITNESS: I'm ready.
 14 BY MR. SLATER:
 15 Q. Looking at the introduction
 16 to this 2006 article authored in part by
 17 a ZHP employee, it starts out stating,
 18 "The quality and safety of
 19 pharmaceuticals can be significantly
 20 effected by the presence of impurities."
 21 Do you see what I just read?
 22 A. That's correct. That's what
 23 it says here.
 24 Q. In the case of ZHP's

<p style="text-align: right;">Page 246</p> <p>1 valsartan, the quality and safety of the 2 valsartan was significantly affected by 3 the presence of nitrosamine impurities, 4 correct? 5 MR. GOLDBERG: Objection to 6 form. Vague. 7 THE WITNESS: Could you 8 please repeat your question? 9 BY MR. SLATER: 10 Q. The quality and safety of 11 the valsartan manufactured by ZHP was 12 significantly effected by the presence of 13 nitrosamine impurities, NDMA and NDEA, 14 correct? 15 MR. GOLDBERG: Objection to 16 form. Vague. 17 THE WITNESS: I do not agree 18 with your opinion. If we are 19 talking about a product of 20 quality, if the manufacturer 21 manufactures the product, if the 22 process approved by the FDA, and 23 the manufacturing was in 24 compliance with the requirements</p>	<p style="text-align: right;">Page 248</p> <p>1 development study was adequate. We 2 disagree. We remind you that common 3 industry practice may not always be 4 consistent with cGMP requirements and 5 that you are responsible for the quality 6 of drugs you produce." 7 When they refer to the cGMP 8 requirements, as we already talked about 9 on the first page of this letter, the FDA 10 indicated that this warning letter 11 summarizes significant deviations from 12 current good manufacturing practice, cGMP 13 for active pharmaceutical ingredients 14 (API), correct? 15 A. The first paragraph you just 16 quoted as the FDA's response that all the 17 way to the end, it says the common 18 industry practice may not always be 19 consistent with cGMP requirement. I saw 20 that in the warning letter. 21 For the second paragraph you 22 just quoted, I could not find where it 23 was in the warning letter. Could you 24 point out where that paragraph came from?</p>
<p style="text-align: right;">Page 247</p> <p>1 of the GMP, then that product 2 would be considered a product of 3 quality. 4 As for the safety of a 5 product, it's up to the science to 6 identify and determine the safety. 7 One, ZHP manufactured this 8 product. FDA did not require us 9 to test NDMA, nor did it set any 10 standard for NDMA. 11 MR. SLATER: Let's go back 12 to the warning letter please. 13 Not that warning letter. 14 Perfect. 15 BY MR. SLATER: 16 Q. Looking now -- rephrase. 17 Going back now to the 18 November 29, 2018 FDA warning letter. 19 Under Section 2, the third paragraph 20 states, "Your response states that 21 predicting NDMA formation during the 22 valsartan manufacturing process required 23 an extra dimension over current industry 24 practice and that your process</p>	<p style="text-align: right;">Page 249</p> <p>1 Q. I just read the third 2 paragraph under Heading Number 2 which 3 states, "Your response states that 4 predicting NDMA formation during the 5 valsartan manufacturing process required 6 an extra dimension over current industry 7 practice and that your process 8 development study was adequate. We 9 disagree. We remind you that common 10 industry practice may not always be 11 consistent" -- actually, you know what, I 12 withdraw that. I just realized what you 13 asked. 14 The second paragraph I 15 referred to is on the first page of the 16 letter. Let's go back to the first page 17 of the letter. 18 It's the second paragraph 19 under where it says, "Dear Mr. Du." 20 It says, "This warning 21 letter summarizes significant deviations 22 from current good manufacturing practice 23 (cGMP) for active pharmaceutical 24 ingredients (API)."</p>

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1 A. That is correct. The
2 paragraph you just quoted was indeed in
3 this warning letter.
4 Q. Let's go back to where we
5 were now on the fourth page of the
6 letter.
7 Where the FDA says, "You are
8 responsible for the quality of drugs you
9 produce," you agree, ZHP is responsible
10 for the quality of drugs that ZHP
11 produces, right?
12 A. Is this your question or
13 you're merely quoting the warning letter?
14 Q. I'm asking, do you agree
15 that ZHP is responsible for the quality
16 of drugs that ZHP produces?
17 A. That is correct. By the
18 time that this last inspection by the FDA
19 took place in 2018, for our manufacturing
20 we passed all the FDA inspections prior
21 to that and it was in compliance with the
22 GMP.
23 MR. SLATER: Go to Page 6
24 now of the letter please.

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1 BY MR. SLATER:
2 Q. The first full paragraph on
3 Page 6 is a one sentence paragraph that
4 says, "FDA placed your firm on Import
5 Alert 66-40 on September 28, 2018."
6 That import alert precluded
7 ZHP from selling its valsartan API
8 manufactured with the zinc chloride
9 process into the United States of
10 America, correct?
11 A. This import ban stopped the
12 manufacturing of API products at our
13 Chuannan facility. Not limited to
14 valsartan. That's a decision made by the
15 FDA.
16 MR. SLATER: Okay. We can
17 take that document down now.
18 Let's go to Exhibit 212.
19 (Previously marked Exhibit
20 ZHP-212.)
21 MR. GOLDBERG: Adam, if
22 you're in between documents, can
23 we just take a two-minute break,
24 not a long break?

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1 MR. SLATER: Sure.
2 MR. GOLDBERG: Thank you.
3 MR. SLATER: Let's go off
4 the record.
5 THE VIDEOGRAPHER: The time
6 right now is 10:08 a.m.
7 We're off the record.
8 (Short break.)
9 THE VIDEOGRAPHER: The time
10 right now is 10:12 a.m. We're
11 back on the record.
12 BY MR. SLATER:
13 Q. With regard to the
14 November 29, 2018 letter written by the
15 FDA, the FDA was not aware, to your
16 knowledge, that as of at least July 2017,
17 multiple people at ZHP were aware that
18 there was NDMA in the valsartan, correct?
19 MR. GOLDBERG: Objection to
20 form. Mischaracterizes the
21 document. Assumes facts not in
22 evidence.
23 THE WITNESS: I do not agree
24 with your opinion.

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1 Yesterday I've already
2 responded to your questions
3 regarding this topic many times.
4 BY MR. SLATER:
5 Q. When you say you don't
6 agree, are you saying that you believe
7 the FDA was aware as of November 29,
8 2018, that people within ZHP knew, at
9 least as of July 2017, that there was
10 NDMA in the valsartan?
11 MR. GOLDBERG: Objection to
12 form. Assumes facts.
13 Mischaracterizes the document.
14 THE WITNESS: Why I do not
15 agree with your opinion, I
16 believe, is that you speculated
17 that ZHP had already known this by
18 2017.
19 I have already responded to
20 this lines of questions that the
21 relevant personnel at ZHP
22 responded to FDA's 483 letter or
23 their questions during the
24 inspection truthfully, which is

<p style="text-align: right;">Page 254</p> <p>1 ZHP had no knowledge of the 2 existence of NDMA in the valsartan 3 process prior to June 2018. 4 BY MR. SLATER: 5 Q. As of November 29, 2018, had 6 ZHP notified the FDA that there were 7 people within ZHP who were aware that 8 there was NDMA in valsartan at least as 9 of July 2017, had that information been 10 provided to the FDA? 11 MR. GOLDBERG: Objection to 12 form -- objection to form. 13 Assumes facts, mischaracterizes 14 the document, and asked and 15 answered yesterday. 16 THE WITNESS: This is a 17 hypothetical question you raised. 18 My response to that will remain 19 the same as in my prior response. 20 BY MR. SLATER: 21 Q. The answer is no, ZHP had 22 not communicated that information to the 23 FDA as of November 29, 2018, correct? 24 MR. GOLDBERG: Objection to</p>	<p style="text-align: right;">Page 256</p> <p>1 Asked and answered yesterday. 2 THE WITNESS: You just put 3 your speculation into your 4 question. And I've already 5 responded to that question many 6 times yesterday and today. 7 With regard to the 8 speculation embedded in your 9 question, I will tell you that 10 ZHP's relevant personnel were not 11 aware of the NDMA existence in 12 2017. They did not become aware 13 of NDMA until June 2018. 14 As I said before, for your 15 hypothetical question that was not 16 complete, I would not respond to 17 this question. 18 BY MR. SLATER: 19 Q. As of today, May 28, 2021, 20 has ZHP ever notified the FDA about the 21 July 2017 e-mail from Jinsheng Lin or 22 provided that e-mail to the FDA? Yes or 23 no? 24 A. No.</p>
<p style="text-align: right;">Page 255</p> <p>1 form. Mischaracterizes the 2 document. Assumes facts not in 3 evidence. Asked and answered. 4 THE WITNESS: My response to 5 this question would be that when 6 ZHP provided the response in 2019 7 or in 2018, they did that based on 8 our knowledge and the facts. 9 Your speculation did not 10 stand. Therefore, I don't think 11 it is necessary for me to respond 12 to this question. 13 BY MR. SLATER: 14 Q. As of today, May 28, 2021, 15 has ZHP, Huahai U.S., Princeton or 16 Solco -- well, let me rephrase. 17 As of today, May 28, 2021, 18 has ZHP notified the FDA that as of 19 July 2017 there were people within ZHP 20 who knew there was NDMA in valsartan, yes 21 or no? 22 MR. GOLDBERG: Objection. 23 Assumes facts not in evidence. 24 Mischaracterizes the document.</p>	<p style="text-align: right;">Page 257</p> <p>1 Q. As of today, May 28, 2021, 2 has ZHP notified Princeton or Solco or 3 Huahai U.S., about the existence of the 4 July 2017 Jinsheng Lin e-mail or provided 5 that e-mail to those companies? 6 A. What are you referring to 7 about -- 8 THE INTERPRETER: The 9 interpreter will start all over 10 again. 11 THE WITNESS: What are you 12 referring to by every company? 13 BY MR. SLATER: 14 Q. As of today, May 28, 2021, 15 has ZHP provided the July 27, 2017, 16 Jinsheng Lin e-mail to Princeton, Solco, 17 or Huahai U.S., or advised any of those 18 three companies about the contents of 19 that e-mail? Yes or no? 20 A. No. 21 Q. As of today, May 28, 2021, 22 do you intend to provide the July 27, 23 2017, Jinsheng Lin e-mail to the FDA? 24 MR. GOLDBERG: Objection to</p>

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1 form -- objection to form. Calls
2 for privileged information.
3 You can answer to the extent
4 that you're not going to disclose
5 information that you discussed
6 with your counsel.
7 THE WITNESS: With regard to
8 this question, it is up to ZHP's
9 QA department, QC department, and
10 other related departments to
11 decide if it is necessary to
12 report that information to the
13 FDA.
14 It is not up to the CEO to
15 decide whether it is necessary or
16 not.
17 In addition, Princeton did
18 not receive such information from
19 the finished dose facilities at
20 ZHP.
21 BY MR. SLATER:
22 Q. You are the CEO of Princeton,
23 Solco, and Huahai U.S. Therefore, all
24 three of those companies are aware of the

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1 existence of the e-mail and its contents,
2 correct?
3 A. Could you repeat your
4 question?
5 Q. You are the CEO of Princeton,
6 Solco, and Huahai U.S., therefore, since
7 you know about and have read the e-mail,
8 all three companies are fully aware of
9 the content of that e-mail, correct?
10 A. I do not agree with your
11 statement. That is because even though I
12 became aware of this e-mail last week, I
13 do not know the background and the
14 technical specifics of this e-mail, nor
15 did the QA department, QC department,
16 technology department or the
17 manufacturing department, or any other
18 relevant department at ZHP, provide any
19 explanation to point out whether this was
20 a quality issue or any other type of
21 issue.
22 I did not receive any
23 official or formal quality assurance
24 feedback through the official channel to

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1 reflect this is an issue.
2 In Princeton, Solco and
3 Huahai U.S., the QA department and the
4 regulatory affairs department conduct
5 their daily business based on the
6 information they receive from the
7 official channel.
8 Q. Have you asked anybody to
9 provide you the background and technical
10 specifics of the July 27, 2017 e-mail
11 from Dr. Jinsheng Lin? Yes or no?
12 MR. GOLDBERG: Objection to
13 form. Asked and answered
14 yesterday.
15 THE WITNESS: I have already
16 responded to this question
17 yesterday.
18 As a CEO, it would not be
19 necessary for me to collect
20 information about the technical
21 specification -- specifics.
22 For the technical specifics
23 it would be the QA department, QC
24 department, technology department,

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1 CEMAT, as well as other related
2 departments to conduct an
3 investigation and make a decision
4 accordingly.
5 This is beyond the scope of
6 my job description or job
7 responsibility.
8 BY MR. SLATER:
9 Q. So the answer to my question
10 is no, you haven't asked to be provided
11 that information?
12 A. The answer to this question
13 would be no. That is because I do not
14 have the technical knowledge to
15 understand. It was also beyond the scope
16 of my job responsibilities.
17 Q. As the vice chairman of the
18 Board of Directors for ZHP and executive
19 vice president of ZHP, do you want ZHP to
20 disclose the July 27, 2017, Dr. Jinsheng
21 Lin e-mail to the FDA? Yes or no?
22 MR. GOLDBERG: Objection to
23 form.
24 THE WITNESS: First of all,

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1 as a vice chair of the Board of
2 Directors at ZHP, we are at the
3 very high level. We did not
4 participate or get involved in the
5 routine activities. It was up to
6 the corresponding departments,
7 such as the technology department,
8 quality department, or people at
9 the professional level to make
10 such decisions.
11 Since you mentioned my title
12 of executive vice president, that
13 was just an interim assignment. I
14 was not supposed to manage daily
15 operations and that was beyond my
16 job responsibilities.
17 BY MR. SLATER:
18 Q. Is the answer yes, I want
19 that information to be provided to the
20 FDA, or is the answer no, I don't want to
21 provide that e-mail to the FDA? Which
22 one is it?
23 MR. GOLDBERG: Objection to
24 form.

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1 THE WITNESS: My answer to
2 your question is that it's up to
3 the ZHP's QA department, QC
4 department, and other related
5 departments to make a decision if
6 a report should be provided to the
7 FDA or not.
8 BY MR. SLATER:
9 Q. The right thing to do is to
10 provide that July 27, 2017 e-mail to the
11 FDA immediately, correct?
12 MR. GOLDBERG: Objection to
13 form. Calls for a legal
14 conclusion.
15 THE WITNESS: I do not agree
16 with your statement. That is
17 because whether it is the right
18 thing to do or not, I do not have
19 the professional knowledge to make
20 such a judgment.
21 BY MR. SLATER:
22 Q. You are the vice chairman of
23 the Board of Directors of ZHP. What is
24 your view as to what the right thing is

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1 to do? Is your view that the e-mail
2 should be provided to the FDA? Yes or
3 no?
4 MR. GOLDBERG: Objection to
5 form.
6 THE WITNESS: I already
7 responded to your question just
8 now.
9 First of all, we do not
10 interfere with the daily
11 operations.
12 Secondly, the QA department,
13 QC department, CEMAT, and other
14 related departments should make a
15 decision on such technical issues.
16 BY MR. SLATER:
17 Q. Do you intend to release the
18 July 27, 2017 e-mail publicly so that the
19 financial markets will be aware of the
20 existence of that document? Yes or no?
21 MR. GOLDBERG: Objection to
22 form. Relevance.
23 THE WITNESS: I already
24 responded to your question just

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1 now.
2 My response will remain the
3 same.
4 BY MR. SLATER:
5 Q. Is the answer yes, we
6 believe that we should provide that --
7 rephrase.
8 Is the answer yes, that as
9 vice chairman of the Board of Directors,
10 I think that the responsible thing to do
11 is to release this information to the
12 financial markets, as you are vice
13 chairman of the Board of Directors of a
14 publicly traded company, or is the answer
15 no, we don't need to release that
16 information?
17 MR. GOLDBERG: Objection to
18 form. That question calls for
19 speculation. It's ambiguous and
20 vague.
21 And you can answer the
22 question.
23 Let me just note for the
24 record that portion of the

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1 transcript moving to a protective
 2 order of any answers about that.
 3 If another question is posed
 4 like that, we'll instruct the
 5 witness not to answer. This is
 6 going so far outside the scope of
 7 what the deposition in this case
 8 should be about, and I'm allowing
 9 the witness to answer the
 10 questions so we get through the
 11 deposition.
 12 However, you've now spent
 13 the better part of two and a half
 14 hours on one document. It's your
 15 entire case, I get that.
 16 But it is certainly
 17 something that I think Judge
 18 Vanaskie would say enough is
 19 enough.
 20 MR. SLATER: I have a new
 21 question.
 22 THE WITNESS: I need to
 23 repeat my answer to your question.
 24 As a vice chairman of the

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1 Board of Directors, I do not
 2 intervene in the specific
 3 operations.
 4 As to whether there would be
 5 an influence in ZHP's specific
 6 actions or whether to take such an
 7 action or not, which is to provide
 8 a report in the financial market,
 9 it depends on the quality
 10 department, the technology
 11 department, as well as other
 12 related departments, as ZHP
 13 decide, whether or not to take
 14 such an action and whether it is
 15 worthwhile to take such an action.
 16 BY MR. SLATER:
 17 Q. Do you believe that the
 18 July 27, 2017 e-mail should be made
 19 public so that the patients who took the
 20 valsartan with the NDMA impurity will be
 21 aware of the existence of the document?
 22 Yes or no?
 23 A. I do not agree with your
 24 statement. That is because with regard

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1 to this e-mail of 2017, ultimately it's
 2 the QA department, QC department, and
 3 other related departments to decide how
 4 to handle this e-mail.
 5 It does not depend on my
 6 personal judgment or speculations,
 7 because I do not have the relevant
 8 knowledge to do so.
 9 Q. Do you as the vice chairman
 10 of the Board of Directors of ZHP, as well
 11 as, as the CEO of Princeton, Solco, and
 12 Huahai U.S., believe that this e-mail
 13 should be made public so that the
 14 patients who took the valsartan with the
 15 NDMA and NDEA impurity will know about
 16 the existence and contents of the e-mail?
 17 Yes or no?
 18 A. As a matter of fact I have
 19 already responded to this question many,
 20 many, many times, as I just did now.
 21 Therefore, I would remain the same in my
 22 response and I would not repeat that
 23 answer.
 24 MR. SLATER: Let's go --

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1 Cheryll, let's take -- oh. We're
 2 actually in this document. Can
 3 you go back to the fourth page of
 4 this document, please,
 5 Exhibit 213?
 6 Perfect.
 7 BY MR. SLATER:
 8 Q. Looking at Exhibit 213, the
 9 November 29, 2018, FDA warning letter. I
 10 want to look again at the third paragraph
 11 under Heading Number 2.
 12 The sentence that states,
 13 "Your response states that predicting
 14 NDMA formation during the valsartan
 15 manufacturing process required an extra
 16 dimension over current industry practice
 17 and that your process development study
 18 was adequate."
 19 With regard to that
 20 statement by the FDA characterizing your
 21 response, isn't it true that, in fact,
 22 the reason that these reactions were not
 23 understood from the outset by ZHP was due
 24 to insufficient process research and

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1 insufficient study in understanding of
2 genotoxic impurities, isn't that the
3 reason?
4 A. I do not agree with your
5 statement. In response to the paragraph
6 you just quoted in the FDA's warning
7 letter, ZHP has already provided an
8 official response in writing. I would
9 rather not provide my personal
10 speculation here.
11 MR. SLATER: Cheryll, let's
12 go to Exhibit 212, please.
13 BY MR. SLATER:
14 Q. Exhibit 212 is a draft of
15 the deviation investigation report titled
16 Investigation Regarding an Unknown
17 Impurity (Genotoxic Impurity).
18 Do you see that on the
19 screen?
20 A. That is correct.
21 I would request a few
22 seconds to review this document.
23 MR. SLATER: Keep time on
24 this, please.

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1 THE WITNESS: I am ready. I
2 have finished the review.
3 BY MR. SLATER:
4 Q. Let's go to Section 5.2, the
5 Bates number, the last three digits is
6 308.
7 Looking now at Section 5.2
8 titled Control Strategy. The document
9 states in part, "Due to insufficient
10 extent and depth of process research at
11 the early stage, as well as insufficient
12 study and understanding of potential
13 genotoxic impurities, only side reaction
14 product and degradation products were
15 studied, and was unaware of the further
16 reaction between degradation products and
17 raw material."
18 That's what this document
19 states, correct?
20 A. Hold on. I'm scrolling to
21 this page.
22 I see this document.
23 Q. That's what the language
24 states, correct?

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1 A. First of all, I don't think
2 this document is an official document.
3 Just it is in the format of a draft.
4 Q. The information I just read
5 was not what ZHP told the FDA, correct?
6 A. I don't know, because I do
7 not get involved in the specifics of a
8 deviation investigation.
9 Q. The information that I just
10 read is not what your letter to the FDA
11 dated August 26, 2018 told the FDA,
12 right?
13 A. I am not sure because I have
14 not compared the two documents to find
15 out the difference.
16 MR. SLATER: Cheryll, let's
17 go back to Exhibit 430. Page 2.
18 Third paragraph. The fifth line
19 down.
20 BY MR. SLATER:
21 Q. You said, "It is this extra
22 dimension over the current industry
23 practice that obscured us from foreseeing
24 this impurity during the process change

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1 from triethylamine process to zinc
2 chloride process."
3 That's what you told the
4 FDA, which is very different from what
5 this Document 212 that we just read
6 states, correct?
7 A. I do not agree with your
8 statement because it says here it
9 requires a more complex -- well, an extra
10 dimension that is more complex research
11 and development.
12 In the previous document we
13 just looked at, it says the R&D, or
14 research and development, was
15 insufficient, but after all, the reason
16 was the lack of knowledge. Therefore, I
17 believe there is just different ways of
18 description between the two documents.
19 And in this letter it was
20 more clear in the description of the
21 cause or the reason. In the previous
22 document that we just looked at, the
23 description there was more in general.
24 I have to emphasize again

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1 that I do not have the ability to conduct
2 an investigation like the QA department
3 does. I only provide my personal opinion
4 based on the statements in those
5 documents.
6 MR. SLATER: Let's go back,
7 if we could, to Exhibit 212, where
8 we were.
9 BY MR. SLATER:
10 Q. Going back to the language
11 in Exhibit 212, the draft of the
12 deviation investigation report, this very
13 clearly states that the problem was
14 "insufficient extent and depth of process
15 research at the early stage, as well as
16 insufficient study and understanding of
17 potential genotoxic impurities."
18 That's the language in the
19 document, correct?
20 A. Well, what you just quoted
21 was indeed what this document says.
22 However, this paragraph continues to say
23 that with the development and progress of
24 science, as well as the in-depth

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1 understanding of research, the potential
2 genotoxic impurities, this issue is
3 gradually understood.
4 MR. SLATER: Let's go off
5 the record.
6 THE VIDEOGRAPHER: The time
7 right now is 11:02 a.m. We are
8 off the record.
9 (Short break.)
10 THE VIDEOGRAPHER: The time
11 right now is 11:17 a.m. We're
12 back on the record.
13 MR. SLATER: Cheryll, let's
14 go to the document ZHP00675949.
15 What exhibit number is this
16 now?
17 (Document marked for
18 identification as Exhibit
19 ZHP-434.)
20 MS. CALDERON: 434.
21 MR. SLATER: Thank you.
22 BY MR. SLATER:
23 Q. Looking now at Exhibit 434,
24 this is an e-mail chain between and among

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1 some people at ZHP and Charles Wang. Do
2 you see that?
3 A. Can you give me a few
4 seconds for me to open this document from
5 the link.
6 MR. SLATER: Time this,
7 please.
8 THE WITNESS: What document
9 number is this? I do not see it
10 in the link.
11 MR. SLATER: 434 is the
12 exhibit number.
13 THE WITNESS: Could you give
14 me a few seconds to review it?
15 I'm ready.
16 BY MR. SLATER:
17 Q. Charles Wang is a
18 toxicologist who was consulted by Min Li,
19 correct?
20 A. That is correct.
21 Q. Charles Wang was employed by
22 another company, Glaxo, at the time that
23 he was consulted by Min Li, correct?
24 A. I'm not sure.

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1 Q. Did you ever speak to
2 Charles Wang?
3 A. Yes.
4 Q. Did you know Charles Wang
5 outside of being introduced to him
6 through Min Li?
7 A. Could you please repeat your
8 question?
9 Q. Did you know Charles Wang
10 independently from being introduced to
11 him by Min Li?
12 Let me ask it differently.
13 Did you meet Charles Wang through Min Li?
14 A. No.
15 Q. How did you meet Charles
16 Wang?
17 A. I met him in a conference.
18 Q. ZHP consulted Charles Wang
19 because you respected Charles Wang as a
20 Ph.D. toxicologist, correct?
21 MR. GOLDBERG: Objection to
22 form.
23 THE WITNESS: What field of
24 work are you referring to when you

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1 said ZHP consulted him?
2 BY MR. SLATER:
3 Q. ZHP consulted Charles Wang
4 with regard to various toxicology
5 questions in 2017 and 2018, correct?
6 A. I'm not sure about that.
7 All I know is that ZHP
8 consulted Charles Wang through Min Li on
9 related knowledge to NDMA in valsartan in
10 toxicology.
11 Q. Looking at Exhibit 319, at
12 the very top of the first page is a
13 July 7th -- rephrase.
14 Looking at Exhibit 434 at
15 the top of the first page is an e-mail
16 dated November 2, 2018, confirming that
17 Charles Wang was paid for the work he did
18 for ZHP, correct?
19 A. That's what this e-mail
20 says, but I have never seen this e-mail
21 before.
22 I do not know whether he has
23 been paid or not either.
24 Q. This e-mail documents that

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1 Charles Wang was paid, as of November 2,
2 2018, for nine reports of 45,000 rmb.
3 That's what the e-mail confirms, right?
4 MR. GOLDBERG: Objection.
5 Foundation.
6 THE WITNESS: That is
7 correct. However, I do not know
8 the specifics. That's what this
9 e-mail says.
10 BY MR. SLATER:
11 Q. What does 45,000 rmb mean,
12 do you know?
13 A. It's a simple question, and
14 I would provide a simple answer.
15 45,000 rmb is the amount in
16 45,000 rmb.
17 Q. What does rmb stand for?
18 A. Rmb stands for the Chinese
19 currency.
20 Q. What is the equivalent of
21 45,000 rmb in United States dollars?
22 MR. GOLDBERG: Objection to
23 form.
24 THE WITNESS: The exchange

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1 rate between rmb and U.S. dollar
2 fluctuates with time.
3 BY MR. SLATER:
4 Q. Can you give me some
5 approximate idea to the best of your
6 ability right now please. Just to give
7 me a range of what 45,000 rmb would
8 correspond to in U.S. dollars. I'm not
9 holding you to the exact number.
10 A. Based on the current
11 exchange rate, 1 USD is equivalent to
12 6.4 rmb based on which you can do a
13 simple calculation.
14 MR. SLATER: Let's go to
15 Exhibit 319, please.
16 (Previously marked Exhibit
17 ZHP-319.)
18 THE WITNESS: Can you allow
19 me to find this document in the
20 link.
21 I have found it. Can you
22 give me a few seconds to review
23 it?
24 MR. SLATER: Fine. We keep

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1 track of all the time. We can
2 take whatever time you need.
3 THE WITNESS: I'm ready.
4 BY MR. SLATER:
5 Q. Looking at Exhibit 319,
6 there is an e-mail from Jim MacDonald,
7 Ph.D., to Charles Wang, following from
8 the back and forth between Dr. MacDonald
9 and Dr. Wang where Dr. Wang had consulted
10 Jim MacDonald.
11 Do you see that e-mail in
12 the middle of the first page here?
13 A. I see this e-mail. It is
14 also the first time I see this e-mail.
15 Q. In this e-mail Dr. MacDonald
16 tells Charles Wang, "I'm afraid I can't
17 be of much help on this case particularly
18 on this time scale. NDMA (or
19 dimethylnitrosamine) is a pretty
20 well-known toxin and animal carcinogen
21 with lots of discussion on permissible
22 levels in drinking water and products.
23 Even though the compound is found in
24 cured meats and some groundwater, the

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1 body of evidence on this suggest pretty
2 clearly that this is a likely human
3 carcinogen at sufficient exposures. The
4 argument that the company would have to
5 make to keep this product on the market
6 will be very difficult with this profile.
7 I'm not exactly sure where one would
8 begin given the very high levels you
9 think they are seeing. I think the
10 strategy I would probably recommend would
11 be to come up with a CMC plan to remove
12 the contaminant (at least to minimally
13 detectable levels) while they recall the
14 existing product and reformulate. I
15 expect this is not what they would want
16 to hear, but unless there is a compelling
17 reason to leave this product on the
18 market, (e.g., only product available to
19 treat a serious life-threatening
20 disease), I would expect that the FDA
21 would ask for a recall. I would be
22 interested to know what happens at the
23 FDA meeting. These things are always
24 very difficult to predict, but this is

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1 not a good position for this product in
2 my view. Hope all is well with you.
3 Best regards, Jim."
4 Do you see what I just read?
5 A. Yes.
6 Q. Then up above that, on
7 July 17, 2018, Charles Wang writes to Jim
8 MacDonald and forwards him a link showing
9 that the valsartan had been recalled. Do
10 you see that?
11 A. Yes.
12 Q. You were speaking with
13 Charles Wang during this time period,
14 correct, June and July of 2018?
15 A. That is correct.
16 Q. And you were aware of the
17 information Charles Wang had and what he
18 had learned from Dr. MacDonald as well,
19 correct?
20 MR. GOLDBERG: Objection to
21 form. Foundation.
22 THE WITNESS: I don't know.
23 I do not have the professional
24 knowledge and he would not discuss

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1 such things with a person that
2 doesn't have professional
3 knowledge like me.
4 BY MR. SLATER:
5 Q. Have you seen the deposition
6 testimony given from Min Li?
7 A. Would you please repeat your
8 question?
9 Q. Have you seen Min Li's
10 deposition transcript and read what he
11 testified to about your interactions with
12 Charles Wang?
13 A. No, I've not seen it.
14 Q. Were you on calls with
15 Charles Wang and Min Li together where
16 all three of you spoke?
17 A. Are you suggesting that we
18 discussed as a group, the three of us?
19 Q. Did you, Charles Wang, and
20 Min Li discuss the NDMA contamination of
21 valsartan together on conference calls or
22 in WeChat?
23 A. First of all, I do not agree
24 with your statement that NDMA is a

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1 contaminant.
2 Secondly, I believe there
3 was some discussion among the three of us
4 in WeChat.
5 MR. SLATER: Take that
6 document down. Let's go to
7 Exhibit 210.
8 It's not coming up on my
9 screen for some reason. There we
10 go.
11 BY MR. SLATER:
12 Q. Looking now at Exhibit 210.
13 This is the deviation investigation
14 report prepared November 5, 2018,
15 according to the front of the document.
16 This was an official report
17 prepared by ZHP with regard to the
18 nitrosamine contamination of the
19 valsartan, correct?
20 A. It is about an investigation
21 regarding unknown impurity of valsartan
22 API TEA process.
23 MR. SLATER: Let's go to
24 Page 11 of 236, please.

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1 Actually, let's go to
2 Page 10 first, Cheryll.
3 THE WITNESS: Please allow
4 me some time to scroll to this
5 page.
6 MR. SLATER: Keep time on
7 this as well please.
8 THE WITNESS: I am ready.
9 BY MR. SLATER:
10 Q. On Page 10, the heading at
11 the top of the page is 3.1.2, NDMA,
12 Physiochemical characteristics and
13 toxicological evaluation of NDMA.
14 And I'd like to now turn to
15 Page 11. And you can see in the second
16 paragraph there's a citation to an
17 article titled Concise International
18 Chemical Assessment Document 38.
19 N-nitrosodimethylamine, published by the
20 World Health Organization in 2002.
21 Do you see that citation?
22 A. Yes.
23 Q. So this is an official
24 report that was prepared by ZHP citing to

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1 that article, correct?
2 A. Judging from what it says in
3 this document, that's correct.
4 MR. SLATER: Cheryll, is it
5 possible, this might take you a
6 moment, can you try to also pull
7 up Exhibit 204, please.
8 (Previously marked Exhibit
9 ZHP-204.)
10 THE WITNESS: Hold on. Let
11 me open this document too, from
12 the link.
13 MR. SLATER: That's not the
14 version that I have in front of
15 me, marked as 204.
16 This is a problem. All
17 right.
18 THE WITNESS: I don't see
19 that.
20 MR. SLATER: No, take --
21 take the document down.
22 All right. Let's go now to
23 Exhibit 321, which is the World
24 Health Organization article that

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1 was referenced in the deviation
2 investigation report.
3 This is Exhibit 321.
4 (Previously marked Exhibit
5 ZHP-321.)
6 THE WITNESS: Hold on. I
7 don't see that in the link.
8 Okay. I see it.
9 Could you allow me a few
10 seconds to review this document?
11 I am ready, but I cannot
12 understand this document.
13 BY MR. SLATER:
14 Q. Let's go to Page 23, please.
15 Top of the page.
16 A. Hold on. Let me scroll to
17 Page 21.
18 MR. GOLDBERG: I think it's
19 23, Jun.
20 THE WITNESS: I'm ready.
21 I'm on this page.
22 BY MR. SLATER:
23 Q. Looking at the top of
24 Page 23 in this article that was cited in

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1 ZHP's own deviation investigation report,
2 it states in the top right, "Therefore,
3 owing to the considerable evidence of
4 carcinogenicity of NDMA in laboratory
5 species, evidence of direct interaction
6 with DNA consistent with tumor formation,
7 and the apparent lack of qualitative
8 species-specific differences in the
9 metabolism of this substance, NDMA is
10 highly likely to be carcinogenic to
11 humans."
12 And that language again is
13 found in an article cited by ZHP in its
14 own deviation investigation report,
15 correct?
16 A. It does not sound the same
17 as the quote you just provided. I did
18 not make the comparison myself.
19 Q. Are you saying that I didn't
20 read the language accurately?
21 A. What you just quoted from
22 this document was right.
23 Q. The World Health
24 Organization article from 2002 concluded

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1 that NDMA is highly likely to be
2 carcinogenic to humans, correct?
3 A. Judging from what it says in
4 this document, the statement you just
5 made is correct.
6 MR. SLATER: Cheryll, can
7 you go back to Exhibit 204,
8 please. I'd like to get to the
9 part where the deviation report,
10 DCE-18001 begins.
11 THE WITNESS: Hold on. Give
12 me some time to review.
13 MR. SLATER: You can do
14 whatever you want. I'm just
15 getting to the document where I
16 want to use it.
17 THE WITNESS: So what's the
18 exhibit number again --
19 MR. SLATER: 204.
20 THE WITNESS: What I opened
21 from the link is different from
22 what you're showing on the screen.
23 BY MR. SLATER:
24 Q. You need to scroll 12 pages

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1 in and you'll find this page.
2 MR. SLATER: Please keep
3 track of all this time. I'm
4 literally going to bring him to
5 one page and identify that the WHO
6 article is identified again. So
7 all this time is unnecessary.
8 MR. GOLDBERG: Counsel, you
9 keep doing that and it is --
10 you're the one directing the
11 witness to the documents.
12 The -- he is scrolling
13 through, and he has told you that
14 he can't find the page you're
15 referring to. Okay.
16 You've got to give the
17 witness a chance to look at the
18 document and get to the page.
19 MR. SLATER: Nobody is
20 stopping him from doing that. The
21 page that I'm --
22 MR. GOLDBERG: This is your
23 time and we're -- and your
24 continual reference to the time,

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1 you don't have to do it every
2 single time the document goes up.
3 Your people are taking -- keeping
4 that time.
5 THE WITNESS: Can you repeat
6 the exhibit number? I go to
7 Exhibit 204, but the one that I
8 see is different from what you
9 have shown.
10 BY MR. SLATER:
11 Q. This is the exhibit. It's
12 Page 12 of the exhibit.
13 A. I would like you to tell me
14 the exhibit number again? What's the
15 number, 200 and what?
16 MR. SLATER: I can't do
17 this. Cheryll, can you help him,
18 please?
19 MS. CALDERON: Mr. Du, it's
20 page -- Exhibit 204, ZHP
21 Exhibit 204.
22 And then you can just -- you
23 can actually just go to the little
24 box at the top that says "of 120."

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1 You can put in the number 12.
2 This is the front of the
3 page. Then you just scroll down
4 to the 12th page.
5 Do you see that? Right
6 there.
7 THE WITNESS: I see it. I
8 see it. We are on different
9 pages.
10 MS. CALDERON: Yes.
11 THE WITNESS: Now I see it.
12 BY MR. SLATER:
13 Q. Looking within Exhibit 204,
14 is the deviation investigation report
15 dated July 20, 2018, it's entitled
16 Investigation regarding a Suspected
17 Genotoxic Impurity of Valsartan,
18 DCE-18001.
19 Do you see that?
20 A. Yes.
21 MR. SLATER: Cheryll, please
22 turn to Page 24 of 33 within
23 this -- this document. It's
24 ZHP0004388.

<p style="text-align: right;">Page 294</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Looking at the bottom</p> <p>3 paragraph on this page, there is a</p> <p>4 citation to the World Health Organization</p> <p>5 article from 2002 that we just looked at.</p> <p>6 Do you see that?</p> <p>7 A. Please allow me to scroll to</p> <p>8 this page before answering your question.</p> <p>9 I'm ready.</p> <p>10 Q. Do you see that the World</p> <p>11 Health Organization article from 2002 is</p> <p>12 cited in the ZHP deviation investigation</p> <p>13 report that we're looking at?</p> <p>14 A. Yes.</p> <p>15 Q. And that's in the section</p> <p>16 titled 4.1.2, Probable Routes of Human</p> <p>17 Exposure and Average Daily</p> <p>18 Intake/Exposure From Environment.</p> <p>19 Do you see that's the</p> <p>20 heading at the top of the page?</p> <p>21 A. Yes.</p> <p>22 Q. And again, that World Health</p> <p>23 Organization article that is cited in</p> <p>24 your company's official report concluded</p>	<p style="text-align: right;">Page 296</p> <p>1 time. Thank you.</p> <p>2 MR. SLATER: Okay. Thanks</p> <p>3 everybody.</p> <p>4 THE VIDEOGRAPHER: The time</p> <p>5 right now is 12:06 p.m. We are</p> <p>6 off the record.</p> <p>7 (Excused.)</p> <p>8 (Deposition concluded at</p> <p>9 approximately 12:06 p.m.)</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 295</p> <p>1 that NDMA is highly -- highly likely to</p> <p>2 be carcinogenic to humans. We just went</p> <p>3 over that, correct?</p> <p>4 A. That is correct.</p> <p>5 MR. SLATER: Thank you. I</p> <p>6 have no further questions at this</p> <p>7 time, subject to my right to</p> <p>8 request continuation or additional</p> <p>9 testimony based on motion practice</p> <p>10 subsequent to the deposition.</p> <p>11 Thank you.</p> <p>12 MR. GOLDBERG: We'll take a</p> <p>13 few minute break and then we'll</p> <p>14 come back in. Can we go off the</p> <p>15 record for a few minutes?</p> <p>16 THE VIDEOGRAPHER: The time</p> <p>17 right now is 11:52 a.m. We are</p> <p>18 off the record.</p> <p>19 (Short break.)</p> <p>20 THE VIDEOGRAPHER: The time</p> <p>21 right now is 12:05 p.m. We're</p> <p>22 back on the record.</p> <p>23 MR. GOLDBERG: We have no</p> <p>24 questions for the witness at this</p>	<p style="text-align: right;">Page 297</p> <p>1</p> <p>2 CERTIFICATE</p> <p>3</p> <p>4</p> <p>5 I HEREBY CERTIFY that the</p> <p>6 witness was duly sworn by me and that the</p> <p>7 deposition is a true record of the</p> <p>8 testimony given by the witness.</p> <p>9</p> <p>10 It was requested before</p> <p>11 completion of the deposition that the</p> <p>12 witness, JUN DU, have the opportunity to</p> <p>13 read and sign the deposition transcript.</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <hr/> <p>12 MICHELLE L. GRAY,</p> <p>13 A Registered Professional</p> <p>14 Reporter, Certified Shorthand</p> <p>15 Reporter, Certified Realtime</p> <p>16 Reporter and Notary Public</p> <p>17 Dated: June 2, 2021</p> <p>18</p> <p>19 (The foregoing certification</p> <p>20 of this transcript does not apply to any</p> <p>21 reproduction of the same by any means,</p> <p>22 unless under the direct control and/or</p> <p>23 supervision of the certifying reporter.)</p> <p>24</p>

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, 217 - 301, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

 JUN DU DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires: _____

 Notary Public

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LAWYER'S NOTES

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